**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

The PATENT APPLICATION of

Inventor : DALY  
Appln. No. : 09/670,781  
Conf. No.: : 6751  
Filed: : September 27, 2000  
Title: : SYSTEM, METHOD AND PACKAGE FOR PROVIDING A  
LIQUID SOLUTION  
  
Group Art Unit : 1761  
Examiner : Weinstein, S.  
Docket No. : 00-39

\* \* \* \* \*

August 26, 2004

**DECLARATION OF DON T. GRANGER, M.D.****UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents  
and Trademarks  
Alexandria, VA 22313-1504

Sir:

Don T. Granger, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.
2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.
3. I am familiar with the SWEET-EASE™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

5. Before the SWEET-EASE™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.
6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.
7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE™ product meets this need.
8. I have personally witnessed the administration of the SWEET-EASE™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE™ product.
9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Don T. Granger, MD  
Don T. Granger, M.D.

8-26-04  
Dated

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor : DALY  
Appln. No. : 09/670,781  
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\* \* \* \* \*

August 26, 2004

## DECLARATION OF NEAL GUTTENBERG, M.D.

UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents  
and Trademarks  
Alexandria, VA 22313-1504

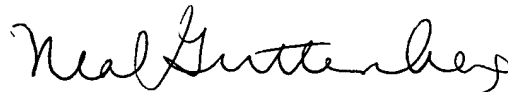
Sir:

Neal Guttenberg, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.
2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.
3. I am familiar with the SWEET-EASE™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

5. Before the SWEET-EASE™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.
6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.
7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE™ product meets this need.
8. I have personally witnessed the administration of the SWEET-EASE™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE™ product.
9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

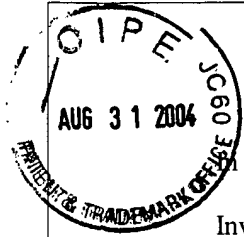
Respectfully Submitted,



Neal Guttenberg, M.D.

Dated

8/26/04



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

re PATENT APPLICATION of

Inventor : DALY  
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 Examiner : Weinstein, S.  
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\* \* \* \* \*

August 26, 2004

**DECLARATION OF M. DAVID YOHANNAN, M.D.**

**UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents  
 and Trademarks  
 Alexandria, VA 22313-1504

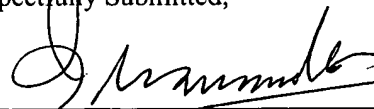
Sir:

M. David Yohannan, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.
2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.
3. I am familiar with the SWEET-EASE™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

5. Before the SWEET-EASE™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.
6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.
7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE™ product meets this need.
8. I have personally witnessed the administration of the SWEET-EASE™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE™ product.
9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,



M. David Yohannan, M.D.

8-27-2004

Dated



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In ~~the~~ PATENT APPLICATION of

Inventor : DALY  
Appln. No. : 09/670,781  
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Examiner : Weinstein, S.  
Docket No. : 00-39

\* \* \* \* \*

August 27, 2004

**DECLARATION OF CATHRINE N. BUSH  
UNDER 37 C.F.R. § 1.132**

Hon. Commissioner of Patents  
and Trademarks  
Alexandria, VA 22313-1504

Sir:

CATHERINE N. BUSH declares that:

1. I have been employed with Children's Medical Ventures, LLC (indirectly, a wholly owned subsidiary of Respironics, Inc.) ("CMV") since its inception in 1991. I am presently the Director of Strategic Marketing. When the SWEET-EASE™ product was conceptualized and introduced to the market, I was the Vice President of Sales and Marketing. I was responsible for the product introduction, including marketing projections and sales/marketing tools.
2. I am familiar with the present U.S. Patent Application Serial No. 09/670,781 filed on September 27, 2000 entitled "System, Method and Package for Providing A Sucrose Solution."
3. The SWEET-EASE™ product was introduced in the market in 2001. Since its introduction in 2001, the SWEET-EASE™ product has experienced amazing success.

The market acceptance of the SWEET-EASE™ product has been surprising. In 2003, only 2 years after introduction, total sales were approximately 2.4 million cups for approximately \$1.7 million in sales. This volume and adoption by the marketplace far exceeds both the typical growth of new products and our original expectations for this product.

4. For comparison purposes, CMV sells a heel warmer under the trademark HEEL HUGGER™. This product is used warm the sole of an infant's foot prior to a heel stick procedure. The HEEL HUGGER™ product has been in the marketplace for 5 years. In 2003, CMV sold approximately 400 thousand units. Therefore, in less than half the time, CMV has sold almost 6 times as many of the SWEET-EASE™ product than of the HEEL HUGGER™ product.
5. I believe that these extraordinary sales results are because the SWEET-EASE™ product provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry. Research validating the effectiveness of sucrose to calm and soothe babies has been available since the late 1980's. However, because there was not a convenient, safe method for sucrose delivery, few hospitals were utilizing it even though it was shown to be effective.
6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Catherine N. Bush

Catherine N. Bush

CATHERINE N. BUSH

Printed Name

8/28/04

Dated



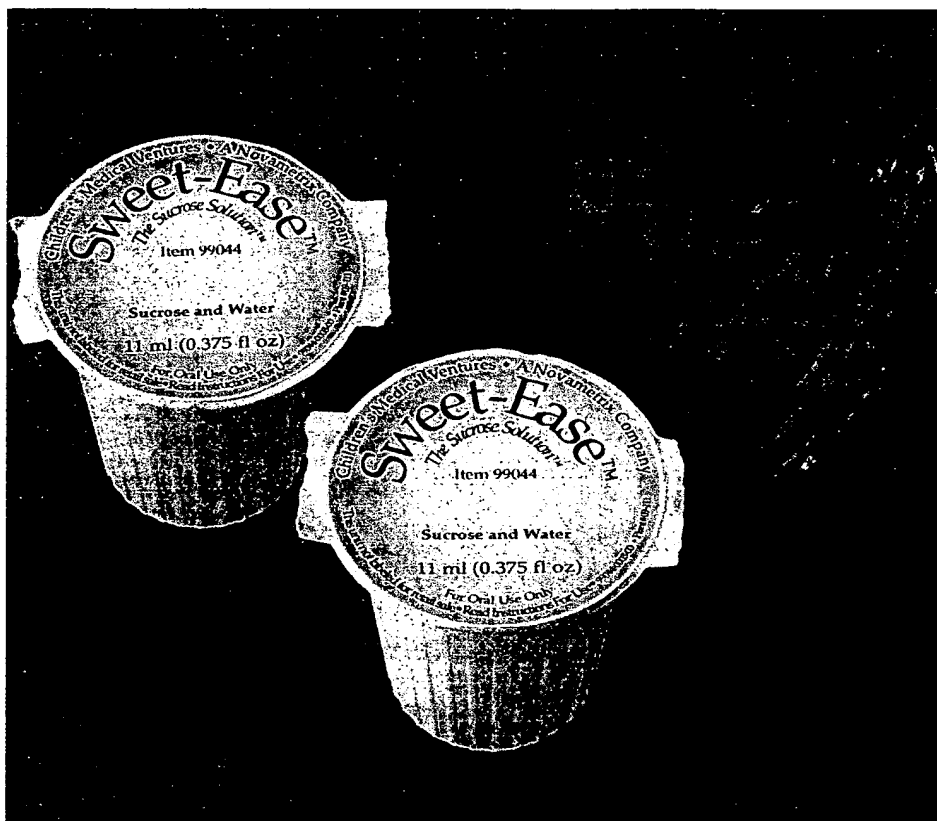


Children's  
Medical  
Ventures

# Sweet-Ease<sup>TM</sup>

The Sucrose Solution<sup>TM</sup>

BEST AVAILABLE COPY



## Features

- Provides a safe and convenient method for oral sucrose delivery
- 24% concentration level\*
- Packaged aseptically
- Preservative free
- 11ml cup with peel off lid is suitable for dipping a pacifier or administration via a dropper
- 6 month shelf life

## Benefits

- May be used in the NICU, PICU and Newborn Nursery
- Helps to calm and soothe babies in distress or during painful procedures \*
- Aseptic packaging decreases risk of contamination
- Prepackaged solution prevents errors in preparation and saves time

\* See bibliography on back.

1001 Murry Ridge Lane  
Murrysville, PA 15668  
[www.childmed.com](http://www.childmed.com)  
[www.respironics.com](http://www.respironics.com)

MEDICAL DISPOSABLES

# Sweet-Ease™

The Sucrose Solution™

## Specifications

- Ingredients: 24% sucrose, 76% water\*\*
- 11ml of sucrose solution per cup
- Guaranteed aseptic in unopened, undamaged package
- Preservative free
- Packaged 200 cups per case (4 boxes of 50)
- Shelf life: six (6) months
- Latex free packaging

## Precautions

- For oral use only (not for injection)
- For hospital use only
- Do not reuse or sterilize
- Store at 40°-90°F (4°-32°C)
- Dispose of product after use

\*\*Over a six (6) month period, concentration may increase to 40%

Patent Pending

## Instructions for Use

- Sweet-Ease™ should be used in compliance with standard hospital practices for oral sucrose delivery.
- See Instructions For Use in each 50 count box.

## Bibliography

Barr RG., Quek VSH., Cousineau D., Oberlander TF, Brian JA., Young SN. Effects of Intra-Oral Sucrose on Crying, Mouthing and Hand-Mouth Contact in Newborn and Six-Week Old Infants. Developmental Medicine and Child Neurology. 1994, 36, 608-618.

Blass EM., Smith BA. Differential Effects of Sucrose, Fructose, Glucose, and Lactose on Crying in 1- to 3-Day-Old Human Infants: Qualitative and Quantitative Considerations. Developmental Psychology. 1992, Vol. 28, No.5, 804-810.

Smith BA., Fillion TJ., Blass EM. Orally Mediated Sources of Calming in 1- to 3-Day-Old Human Infants. Developmental Psychology. 1990, Vol. 26, No.5, 731-737.

Taylor S. Aseptic Cartons. Food Product Design: Focus On New Technologies. 1999.

## Samples

Samples of Sweet-Ease™ are available. Please call Children's Medical Ventures at 800-345-6443 for further information.

## Ordering Information

ITEM NO.	DESCRIPTION	QTY.
99044	Sweet-Ease™ The Sucrose Solution™	200/CS

### TO ORDER

CALL 1-800-345-6443  
or 1-724-387-4000

[www.childmed.com](http://www.childmed.com)  
[www.respironics.com](http://www.respironics.com)

1001 Murry Ridge Lane  
Murrysville, PA 15668